

510(k) Summary**SENTINEL™ Spinal System****Submitted By:**

Life Spine
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AUG 11 2009**510(k) Contact:**

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Date Prepared:

April 03, 2009

Trade Name:

SENTINEL™ Spinal System

Classification:

KWP, 21 CFR 888.3050, Class II, Spinal Interlaminar
Fixation Orthosis.

Predicate Devices:

Synthese Synapse System (K070573), Biomet Altius
OCT System (K043229), Stryker Spine OASYSTM
System (K032394), and Depuy SUMMITTM OCT Spinal
System (K010681)

Device Description:

The SENTINEL™ Spinal System is a temporary, titanium alloy (6AL-4V-ELI per ASTM F 136), multiple component system comprised of a variety of non-sterile, single use implantable components. When assembled, the components create a rigid structure providing stabilization and promote spinal fusion. The system consists of an assortment of occipital plates, occipital bone screws, polyaxial screws, hooks, rods, and locking caps.

Intended Use of the Device:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput – T3), the SENTINEL Spinal System, when properly used, is intended for: Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; spinal stenosis; fracture/dislocation; Atlanto/axial fracture with instability; occipitocervical dislocation; revision of previous cervical spine surgery; and tumors.

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.



K090343 P2042

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The use of polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Material:

Manufactured from medical grade titanium alloy described by ASTM F136 (Ti 6Al-4V-ELI) implant grade titanium alloy.

Substantial Equivalence:

The SENTINEL Spinal System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Life Spine
% Mr. Daniel Predick
Project Engineer
2401 W. Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

AUG 11 2009

Re: K090343

Trade Name: SENTINEL™ Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: July 23, 2009
Received: July 28, 2009

Dear Mr. Predick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

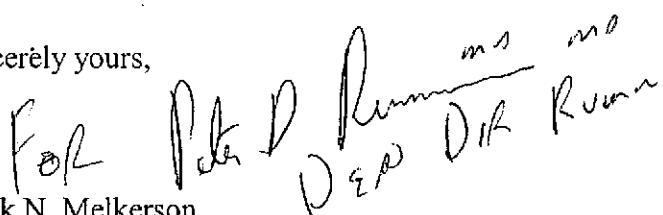
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K090343

Device Name: **SENTINEL™ Spinal System**

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The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

Prescription Use x
(Part 21 CFR 801 Subpart D)

And/Or

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

 (Ex T for MKM)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090343